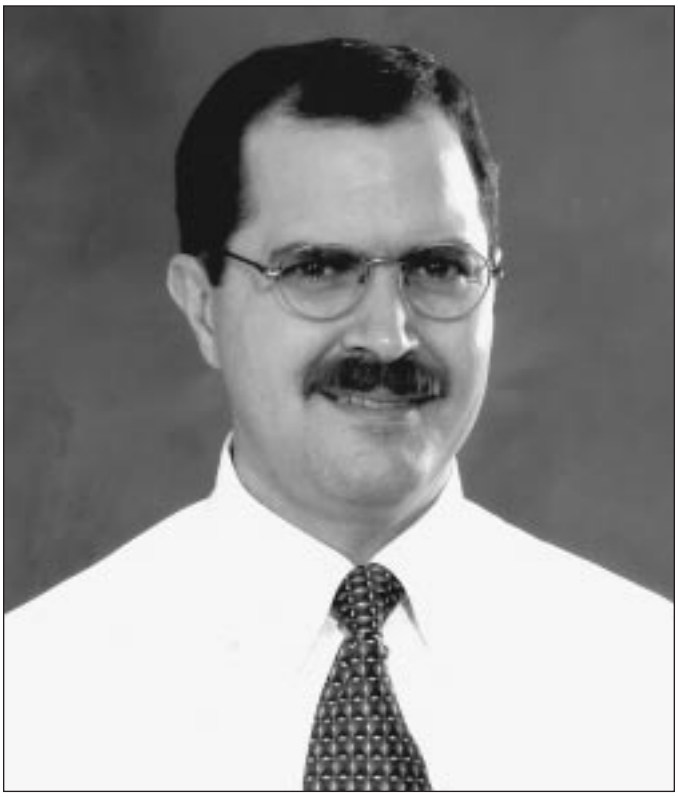
GUEST EDITORIAL

Introduction to the single-topic issue on functional electrical stimulation



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Prologue

This single-topic issue of the *Journal of Rehabilitation Research and Development* on functional electrical stimulation (FES) is an attempt to identify novel ways to address neuromuscular dysfunction through innovative technologies (neuroprostheses based on electrical stimulation) and biological or pharmacological interventions (neural regeneration, gene therapy, and stem cell research). Although heavily biased toward application of FES technology after spinal cord injury (SCI), the selection of papers is based fundamentally on the notion that the key to real advancement in the field of functional restoration after paralysis may well involve combinations of what have too often been considered separate and isolated approaches.

Since advances in the biological and neurosciences are changing the physical characteristics of people with spinal cord injuries, current stimulation and surgical techniques (which assume intact peripheral innervation and a static deficit) may need to change to remain effective tools for the clinician. Technologies that work today may need to be redesigned to better serve a user population that will be changing as new biological or pharmacological therapies become more widespread and continually improve the neurological condition of persons with central nervous system (CNS) trauma. Similarly, it is likely that electrical stimulation and the technical advances in neural engineering may have significant impact on the effectiveness of new therapeutic agents. As progress in both areas continues, we need to explore how to best take advantage of the benefits of all available modalities for enhancing function.

Great advances are being made in the fields of regeneration, stem cell research, neuromodulation, and neuroplasticity, but FES is often ignored as a treatment option when the future of restorative medicine is discussed. As regenerative therapies mature and become more widely available, more and more individuals with SCI are likely to exhibit function resembling neurologically incomplete injuries that can be further improved by FES. The goal is to find ways for technical interventions to work together with emerging regenerative therapies and to combine biological with FES treatment to maximize function.

In the long run, the most effective treatment strategy will be to find ways for technical and biological approaches to interact and amplify the effectiveness of each other—by directing growth of axons, exerting protective effects, or filling in the gaps left when incomplete reconnections are established. In short, we need a

dialog that promotes interaction and fosters discussion so that we can find the common ground that connects restorative and regenerative techniques.

The difficulty lies in finding ways to forge a working marriage between neuroprosthesis technology and restorative biology that takes advantage of the strengths of each in a complementary, rather than competitive, manner. The total of a combined approach will surely be greater than the sum of the individual parts.

Content and Structure

All contributions to this single-topic issue attempt to address some aspect of a new generation of neuroprostheses to maximize the abilities of individuals with SCI or other central nervous system disorders. Most of the articles were derived from oral presentations given at the 16th Annual Case Western Reserve University (CWRU) Applied Neural Control Research Day, and the 6th Annual Scientific Meeting of the International FES Society (http://www.ifess.org), which were held jointly in June 2001 by the Cleveland FES Center (http://www.fesc.org), a consortium consisting of the Louis Stokes Cleveland VA Medical Center, MetroHealth Medical Center, and CWRU. As such they were not subjected to the traditional peer-review process, but underwent a rigorous internal review by the editorial staff of the *Journal of Rehabilitation Research and Development* and guest editors of the single-topic issue.

CWRU Applied Neural Control Research Day is a one-day symposium that gathers the faculty, collaborators, and students pursuing research at Case Western Reserve University to highlight their ongoing work in the area of neural control and neuroprostheses. Historically, this meeting has included detailed descriptions of fundamental work conducted at the Applied Neural Control Laboratory at CWRU and more clinically oriented work at the Motion Study Laboratory at the Cleveland VA Medical Center, and the FES Center Clinical Laboratories at the MetroHealth Medical Center. The symposium this year consisted of four in-depth presentations of research taking place at CWRU and its affiliates, interactive presentations by graduate students and faculty, and a special lecture by an established and internationally recognized researcher who is charged with reflecting on lessons from his own career for young biomedical engineers entering the field of neuroprosthetics. The first four papers in this single-topic issue span the range of research activity at CWRU from basic science through technical development and clinical deployment. First, Anthony DiMarco and colleagues describe work toward a novel respiratory neuroprosthesis. This paper is followed by a presentation of the development and initial clinical and technical performance of a neuroprosthesis for standing and transfers after SCI by John A. Davis, Jr., et al., who summarize the results of a small-scale Phase II multicenter trial. Dr. Robert Kirsch and colleagues describe new work toward the control of the proximal arm for a new neuroprosthesis for individuals with high tetraplegia. Finally, Ravi Bellamkonda et al. present their concept and initial results toward the development of hybrid neural interfaces designed to make connections and communicate with regenerating neurons.

IFESS 2001, on the other hand, consisted of investigator-initiated platform presentations and interactive poster sessions for scientific papers, as well as invited speakers. Each day concluded with a special session organized by the Cleveland VA Center of Excellence in FES to address a topic area important for the future of the field. The next three papers in this single-topic issue were derived from the three special sessions at IFESS 2001, which in contrast to a traditional biomedical engineering meeting, featured speakers who, by design, are not biomedical engineers. The keynote address at IFESS 2001, which dealt specifically with the interface between neurobiology and technology, is presented here as a special guest editorial.

The theme for IFESS 2001 was “Envisioning a New Century of Breakthroughs,” to emphasize a forward-looking perspective. Monumental strides have been made in the development, successful application, and commercialization of FES technologies and neural prostheses over the past 10 years, with sensory, motor, and neuromodulation systems gaining FDA approval and CE marks and approaching widespread clinical

use. But the meeting was designed to resist the temptation to rest on these past accomplishments and strove to be more speculative. Invited speakers were charged with identifying the major challenges that need to be overcome to make quantum leaps in the functionality, acceptability, and profitability of neuroprostheses, and discussions were directed toward the collective future of the field.

In keeping with this theme, the first special session speculated on mutual opportunities for the convergence of technical and biological approaches to functional restoration. Organized by Hunter Peckham and William Heetderks, the session entitled "Neural Repair and Functional Restoration" directly explored the ways biological mechanisms of neural repair and electrical stimulation might work together to maximize the restoration of function after CNS damage. It addressed the issues involved with combining emerging regenerative therapies (i.e., gene therapy, stem cell transplants, and other biological or pharmacological approaches) and restorative techniques (i.e., functional electrical stimulation and neural engineering) to maximize the abilities of individuals with SCI or other central nervous system trauma. The session focused directly on speculative methods of integrating regenerative and restorative techniques. Since technologies that work today may need to be redesigned to better serve a user population that will be changing as new biological or pharmacological therapies become more widespread and it is likely that electrical stimulation and the technical advances in neural engineering may have significant impact on the effectiveness of new therapeutic agents, the session explored how to best take advantage of the benefits of all modalities for enhancing function after CNS trauma. The ensuing discussion identified new ways for technical interventions to work together with emerging regenerative therapies and to combine biological with FES treatment modalities to maximize function following paralysis. That special session resulted in the paper entitled "At the Interface: Convergence of Neural Regeneration and Neural Prostheses for Restoration of Function," which suggests several starting points for regenerative biology and neuroprosthetic technology to begin to work together for the benefit of people with paralysis and motor dysfunction.

The next paper was derived from the special session entitled "Emerging Clinical Applications for Restoration of Function," which focused on the scientific principles and mechanisms underlying the desired clinical effect of electrical stimulation, and the scientific and technological challenges that limit current application of the technology. The session and resulting paper of the same name by Warren Grill et al. highlighted innovative uses of FES that are just now on the verge of clinical viability and deal with novel techniques or applications that are still under investigation, but which have potential for long-term clinical impact.

The last special session of IFESS 2001 was an opportunity to explore the successes and shortcomings of presently deployed neural prostheses, as well as to identify desirable design features and attributes of future neural prostheses from the consumers' perspective. Organized by Kevin Kilgore and facilitated by Marcia Scherer, this panel of current and potential neuroprosthesis users described in their own words their attitudes about where our research and development energies should be spent. The purpose of this panel discussion was to allow consumers of neuroprostheses (users and nonusers of electrical stimulation devices) to identify their priorities for future developments and express their personal objectives for new system designs. The neuroprosthesis users on the panel provided a candid and unvarnished look at the limitations of current neuroprostheses, thus challenging the scientific and engineering community by identifying directions for continued research development. Consumers (real or potential) of neuroprostheses freely expressed their frustrations with their level of function and critically analyzed the design features and functions of most importance to them of the systems they use or desire. The session was organized around a series of targeted questions to determine the clinical needs of individuals with motor impairments caused by SCI, with specific reference to those that can be addressed by FES technologies. Questions were constructed and the

discussion directed to identify each individual's perceived relationship between the "cost" of the technology (in terms of time, money, inconvenience, etc.) and the function provided by the technology. These telling insights are organized and presented in the paper entitled "Neuroprosthesis Consumers' Forum: Consumer Priorities for Research Directions."

Finally, Andres Lozano's keynote address entitled "Deep Brain Stimulation: Challenges to Integrating Stimulation Technology with Human Neurobiology, Neuroplasticity, and Neural Repair" addressed the clinical and technical challenges of central nervous system stimulation for neuromodulation, tremor, epilepsy, and other movement or seizure disorders. In the resulting paper, which is offered as an invited commentary, he presents his vision on the interaction and integration of biological and technological interventions and specifically enumerates the potential of and recent developments in deep brain stimulation, as well as the priorities for future research.

Thus, in combination, all of these papers identify the challenges and opportunities for developing the next generation of neural prostheses.

Epilogue

Collectively, this compilation of articles represents a forward-looking perspective on the field of neuroprostheses, FES, and restorative technologies developed to maximize independence function after CNS insult. The total of these papers, and the breakthroughs they envision for the future, should result in something greater than the sum of their individual parts.

The time to develop complementary strategies and explore novel ways to combine emerging biological therapies with existing assistive technologies involving neuroprostheses and electrical stimulation is long overdue. The idea is simply that the most successful treatments for spinal cord injuries and other neuromuscular dysfunctions in the future will necessarily combine all sorts of complementary interventions, including regenerative therapies and restorative technologies. The challenges exist for all of us to pursue our common goal with open minds, abandon our parochial world-views, and remove the self-imposed barriers to progress in order to find new paradigms for working together.

ACKNOWLEDGMENTS

This single-topic issue was made possible with the support of the Rehabilitation Research and Development Service of the Department of Veterans Affairs, without which the opportunity to capture their unique content would have been lost. Special thanks also to Lisa Cash for her help in interpreting the oral presentations upon which many of these articles are based and synthesizing them into cogent, coherent, and self-contained manuscripts, and to Laura Polacek for her assistance in their transcription.

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